UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

ANGELINE CACCHILLO,

Plaintiff,

vs. **Civil Action No. 1:10-CV-01199 (TJM/RFT)**

INSMED INC.,

Defendant.

THOMAS J. McAVOY,
Senior United States District Judge

DECISION & ORDER

I. INTRODUCTION

Plaintiff ANGELINE CACCHILLO commenced this action after her participation in a phase II clinical trial of Defendant INSMED INC.'s investigational new drug IPLEX™. Following the Court's decision on Defendant's Fed. R. Civ. Pro. 12(b)(6) motion, see dkt. # 41, only Plaintiff's breach of contract, fraud, and negligent misrepresentation claims remain. Defendant moves for summary judgment dismissing the remaining claims. Dkt. # 64. Plaintiff opposes the motion, dkt. # 71, and Defendant has replied. Dkt. # 73. The Court has considered all of the papers submitted on this motion in rendering this Decision and Order.

II. STANDARD OF REVIEW

On a motion for summary judgment the Court must construe the properly disputed facts in the light most favorable to the non-moving party, see Scott v. Harris, 127 S. Ct.

1769, 1776 (2007), and may grant summary judgment only where "there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see O'Hara v. National Union Fire Ins. Co. of Pittsburgh, PA, 642 F.3d 110, 116 (2d Cir. 2011).

III. BACKGROUND[1]

a. Parties

Plaintiff Angeline Cacchillo ("Plaintiff") was diagnosed with Type 1 Myotonic Muscular Dystrophy Type 1 ("MMD1") in July 2005. MMD1 is a degenerative genetic neuromuscular disease which, over an extended period of time, breaks down a victim's neuromuscular system.[2] There is no FDA accepted treatment for MMD1 and only superficial treatments designed to minimize the discomfort of MMD1. According to Dr. Victoria Lawson, Mrs. Cacchillo's current physician, Plaintiff's "prognosis is poor. She will have progressive degeneration, neural degeneration related to weakness, and she will have a shortened life span." PSOF ¶ 5.

Insmed Inc. ("Insmed" or "Defendant") is a research-based pharmaceutical company located in Richmond, Virginia. Insmed scientists developed the drug IPLEX™

[1]Except where indicated otherwise, the Background facts are taken from the parties' Local Rule 7.1(a)(3) Statements of Undisputed Material Facts ("SOF"). Where Defendant's SOF is cited ("DSOF"), it is in those circumstances where the asserted fact is admitted by Plaintiff, or where the record evidence supports the assertion. Where Plaintiff's Counter-SOF is cited ("PSOF"), it is in those circumstances where the asserted fact is admitted by Defendant, or where the record evidence supports the assertion. Disputed facts are viewed in the light most favorable to Plaintiff.

[2] The disease makes it increasingly difficult to do anything involving the use of muscles, including walking, manipulating objects, swallowing, and breathing. PSOF ¶ 2. It also breaks down the heart's ability to pump blood, impairs cognition, and causes the patient's death over a period of years. Id. ¶ 3.

(mecasermin rinfabate [rDNA origin] injection) ("IPLEX").[3] On December 12, 2005, the Food and Drug Adminstration ("FDA") approved IPLEX for the treatment of growth failure in children with severe primary IGF-1 deficiency ("severe IGFD") or with growth hormone ("GH") gene deletion who have developed neutralizing antibodies to GH ("GHIS"). One year before the FDA approval, Genentech, Inc. and Tercica, Inc. instituted a patent infringement suit against Insmed and others with respect to certain patents underlying IPLEX. See Genentech, Inc. v. Insmed, Inc., No C-04-5429 (N.D. Cal. filed Dec. 23, 2004). On December 6, 2006, a jury returned a verdict finding that Insmed had infringed the various patents at issue. In March 2007, Insmed entered into a settlement agreement pursuant to which Insmed agreed to cease marketing IPLEX to patients with GHIS or IGFD. Insmed was permitted, under the terms of the settlement agreement, to develop and undertake clinical trials for certain limited conditions including MMD1 and Amyotrophic Lateral Sclerosis ("ALS").

After the March 2007 settlement, Insmed maintained an expanded access program ("EAP") by which it provided IPLEX to patients in Italy suffering from ALS through Italy's Named Patient Program, PSOF ¶ 32, and to a patient in France suffering from leprechaunism.[4] On March 10, 2009, the FDA announced its position of allowing patients with ALS expanded access to IPLEX, DSOF ¶ 168, and Insmed thereafter provided

[3]IPLEX, a combination of two substances: human insulin-like growth factor 1 (IGF-1) and human insulin-like growth factor-binding protein-3 (rhIGFBP-3), is a unique drug engineered as a synthetic replacement for hormones and proteins which are not produced by individuals afflicted with neuromuscular disorders like MMD1. PSOF ¶ 8.

[4]Leprechaunism is "a rare lethal familial condition marked by slow physical and mental development, the elfin facies suggested by the name (wide-set eyes, low-set ears, and hirsutism), and severe endocrine disorders, such as enlargement of the clitoris and breasts in females and of the phallus in males. Also called Donohue's syndrome." http://medical-dictionary.thefreedictionary.com/leprechaunism

expanded access of IPLEX to ALS patients in the United States for a relatively short period of time.

b. "Compassionate Use"

Much of this case surrounds the term "compassionate use" in relation to obtaining an investigational drug that has not been approved by the FDA. See Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 495 F.3d 695, 698-99 (D.C. Cir. 2007) (*en banc*), cert. denied, 128 S. Ct. 1069 (2008)(discussing the FDA clinical trial approval process). "Compassionate use" is not defined in the FDA's regulations but rather is a colloquial term used to refer to two mechanisms by which "expanded access" to promising investigational drugs may be granted by the FDA. Id.; see 21 U.S.C. § 360bbb; 21 C.F.R. Part 312; 21 C.F.R. § 312.300 *et seq*. One mechanism is a single patient investigational new drug application ("single patient IND application"), and the other is a treatment investigational new drug application ("treatment IND application"). See Investigational New Drug (IND) Application, www.FDA.gov.[5]

A single patient IND application is submitted by a physician on behalf of a patient for FDA approval of access to an investigational drug. See Physician Request for an Individual Patient IND under Expanded Access for Non-emergency or Emergency Use, www.FDA.gov.[6] The governing section of the United States Code provides in pertinent part:

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[5]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/default.htm (last accessed 2/13/12).

[6]http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/InvestigationalNewDrugINDApplication/ucm107434.htm (last accessed 2/13/12).

Expanded access to unapproved therapies

* * *

(b) Individual patient access to investigational products intended for serious diseases

Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer . . ., and any manufacturer . . . may, after complying with the provisions of this subsection, provide to such physician an investigational drug . . . for the . . . treatment of a serious disease or condition if–

> (1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to . . . treat the disease or condition involved, and that the probable risk to the person from the investigational drug . . . is not greater than the probable risk from the disease or condition;
>
> (2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug . . . in the case described in paragraph (1);
>
> (3) the Secretary determines that provision of the investigational drug . . . will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and
>
> (4) the sponsor, or clinical investigator, of the investigational drug . . . submits to the Secretary a clinical protocol consistent with the provisions of section 355(i) or 360j(g) of this title, including any regulations promulgated under section 355(i) or 360j(g) of this title, describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

21 U.S.C. § 360bbb(b).

"When a physician would like to submit an Investigational New Drug application (IND) to obtain an unapproved drug for an individual patient, he or she should first ensure that the manufacturer of the unapproved drug is willing to provide the drug. Without the consent of the manufacturer, the unapproved product will not be available to the patient." Physician Request for an Individual Patient IND under Expanded Access for Non-emergency or Emergency Use, www.FDA.gov. Consent of the manufacturer is

obtained by way of a "drug-supply reference letter" stating that the manufacturer is willing to provide the drug for a defined treatment period. PSOF ¶¶ 24-27. The letter also allows the physician and the FDA to cross-reference the information about the drug developed during any clinical trials. Id. The drug supply reference letter does not need to assert that the drug has been determined an effective treatment for the patient's condition or make any representation concerning the patient's likelihood of improvement on the drug. PSOF ¶ 28; see 21 U.S.C. §360bbb(b)(1).

A "treatment IND" is governed by 21 U.S.C. § 360bbb(c), which provides in pertinent part:

> (c) Treatment investigational new drug applications . . .
>
> Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug . . . for eligible patients (referred to in this subsection as an "expanded access protocol"), the Secretary shall permit such investigational drug . . . to be made available for expanded access under a treatment investigational new drug application . . . if the Secretary determines that--
>
> > (1) under the treatment investigational new drug application . . . , the investigational drug . . . is intended for use in the . . . treatment of a serious or immediately life-threatening disease or condition;
> >
> > (2) there is no comparable or satisfactory alternative therapy available to . . . . treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;
> >
> > (3)(A) the investigational drug . . . is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 355(i) of this title . . . ; or
> >
> > > (B) all clinical trials necessary for approval of that use of the investigational drug . . . have been completed;
> >
> > (4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug . . . for the use described in paragraph (1) with due diligence;

> (5) in the case of an investigational drug . . . described in paragraph (3)(A), the provision of the investigational drug . . . will not interfere with the enrollment of patients in ongoing clinical investigations under section 355(i) or 360j(g) of this title;
>
> (6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1).

21 U.S.C. § 360bbb.

c. Plaintiff's Claims

In the Complaint, Plaintiff alleges, *inter alia,* that Defendant fraudulently induced her to enter a clinical trial (exploring the use of IPLEX to treat MMD1) with the false promise to support her compassionate use application after the clinical trial, Compl. ¶¶ 195-197; negligently represented that it would support her compassionate use application, id. ¶¶ 198-200; and breached the contract between Plaintiff and Defendant which called for Defendant to support Plaintiff's compassionate use application. Id. ¶¶ 201-03. In opposition to the present motion, Plaintiff contends that Defendant's promise and representation was more than that it would support her compassionate use application, but rather that it would supply Plaintiff with IPLEX at the end of the trial if she did well on the drug. See Pl. MOL, p. 30.[7] In this regard, Plaintiff asserts that the agreement was that Insmed would supply her with IPLEX "until a better treatment is found, the patient passes away, the treatment stops working, or the patient is cured." Id. According to Plaintiff, the IPLEX would be provided to her "by one of three (3) paths; 1) through a [Phase III] clinical trial, 2) compassionate use, or 3) normal channels upon mass market approval of the drug." Id.

[7]("Insmed's offer was that if Mrs. Cacchillo performed her obligations as a trial subject and did well on IPLEX, Insmed would provide her with IPLEX treatment at the end of the trial.").

d. Plaintiff's Early Attempts to Obtain IPLEX

Plaintiff has been trying to obtain IPLEX since she first heard of it, which was shortly after she was diagnosed with MMD1 in July 2005 . DSOF ¶¶ 1-2. At that time, Plaintiff learned of a clinical trial of IPLEX for the treatment of MMD1 being conducted by the University of Rochester Medical Center ("URMC")("Phase IIA Trial"). Id. Plaintiff contacted the URMC[8] and spoke with the Phase IIA Trial's Clinical Trial Coordinator, Christine Quinn, in an attempt to participate in the trial. Id. ¶ 4. Plaintiff was disappointed to learn that she missed the maximum age eligibility (sixty years) by three months. Id. ¶ 5. Ms. Quinn told Plaintiff's husband that "[y]ou may want to look into compassionate use." RC[9] pp. 18-19.

e. Insmed's Representations

Aware that IPLEX was a possible treatment for MMD1, Plaintiff and her husband followed the development of IPLEX on the Internet. Mr. Cacchillo "constantly would go to Insmed's web site on IPLEX." DSOF ¶ 6. Mr. Cacchillo subscribed to Insmed's website, whereby he received press releases and other information directly from Insmed. Id. ¶ 7. Mr. Cacchillo printed and saved a number of articles, press releases and other materials concerning Insmed and/or IPLEX between December 2005 and December 2008. Id. ¶ 8.

A May 3, 2007 press release stated: "During the six months of treatment, 5 out of 6 [MMD1 trial subjects] experienced an improvement in lean muscle mass. Patients also reported improvement in gastrointestinal function, endurance and cognitive function during

[8]Plaintiff's then-treating physician had no knowledge of the study or IPLEX and was not interested in it so the Cacchillos pursued IPLEX on their own. DSOF ¶ 3.

[9]"RC" is a reference to Robert Cacchillo's deposition transcript.

treatment with IPLEX." Def. Response to PSOF ¶ 22. The website also contained a number of statements concerning Insmed's provision of IPLEX to ALS patients Italy. RC pp. 90, 186-87; Ex 36.[10]

In addition, Mr. Cacchillo saw solicitations on Insmed's website to physicians who might have been interested in securing compassionate use access to IPLEX for patients. RC p. 98, Ex 29; AC[11] pp. 84-85. In this regard, in August 2007 Mr. Cacchillo read a posting on Insmed's website indicating that IPLEX could be accessed by MMD1 patients or their physicians through one of two FDA approved methods regulations governing investigational new drugs.[12] Mr. Cacchillo and Plaintiff understood the press release as indicating that IPLEX could be made available to MMD1 patients by a mechanism they understood as "compassionate use." RC p. 154-55; R. Cacchillo 12/17/10 Aff., ¶¶ 2-8 (affidavit attached as Def. Ex 14). The pertinent language of Insmed's website stated:

> Insmed has discussed regulatory alternatives with the FDA. Investigational drugs such as IPLEX can be accessed by patients . . . . A physician may submit a IND application to [the] FDA for the treatment of an individual patient under a single patient IND, sometimes known as "compassionate use." The process for applying for a single patient IND is outlined at [the FDA's website (link hereto provided)]. Should a physician decide to seek IPLEX for the treatment of a patient, he or she should contact Insmed. Insmed will provide a drug supply reference statement that acknowledges Insmed's commitment to the requesting physician. Single patient IND applications would then be submitted to the division of neurology products at the FDA for consideration. Patients or physician inquiries regarding IPLEX should be directed to concal@Insmed.com.

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[10]Robert Cacchillo is the only known witness with personal knowledge of the content of Insmed's website prior to December 2008.

[11]"AC" is a reference to Angeline Cacchillo's deposition transcript.

[12]This language of this web site posting was purportedly the same a February 12, 2009 Insmed press release which Mr. Cacchillo printed in part and copied by hand in part. The February 12, 2009 press release is discussed in more detail in the text, *infra*.

R. Cacchillo 12/17/10 Aff., ¶ 8 (brackets in affidavit).

f. Subsequent Attempts to Obtain IPLEX

In May 2007, Plaintiff and her husband called Ms. Quinn at the URMC, apparently to inquire about obtaining IPLEX. The Cacchillos prepared notes for the call to ensure that everything was covered during the call. DSOF ¶ 9. In these notes, Mrs. Cacchillo indicated that she had previously spoken to Ms. Quinn regarding the trial but did not qualify; had been following the updates on the clinical trial; that she was still "very interested" in participating and was prepared to participate "on an unofficial basis at no cost to the trial;" and that she "would be willing to do whatever is required of the trial, including being available to go to Rochester as much as needed." Id. ¶ 10. According to Mr. Cacchillo, Ms. Quinn told them that IPLEX was not available off-label.[13] Id. ¶ 11.

On August 6, 2007, the Cacchillos traveled to the Cleveland Clinic in Cleveland, Ohio, to meet with Dr. Lan Zhou, a neurologist who specialized in treating MMD1. DSOF ¶ 12.[14] The purpose of the visit was primarily to obtain off-label access to IPLEX. Id. ¶ 14.[15] The Cacchillos brought with them a "pile of stuff" concerning IPLEX with the hope that Dr. Zhou would prescribe IPLEX for Mrs. Cacchillo off-label, id. ¶ 16, which she did not do.

After the meeting, Dr. Zhou contacted Dr. Richard Moxley, the Chief Investigator of the MMD1 trial at the URMC, and inquired about IPLEX. Dr. Moxley informed Dr. Zhou that IPLEX was not available in the United States and that if she wanted more information

[13] "Off-label" refers to the use of an FDA- approved drug by a physician to treat a disease other than that for which the drug was approved.

[14]The visit was Plaintiff's only meeting with Dr. Zhou. DSOF ¶ 13.

[15]When the Cacchillos met with Dr. Zhou, they were not aware that there would be any further clinical trials of IPLEX, and thus Mrs. Cacchillo's participation in any further trials was not discussed. DSOF ¶ 15.

she could contact Insmed directly. Id. ¶ 17. Dr. Moxley suggested that Dr. Zhou contact Insmed CEO Ronald Gunn. Dr. Zhou then called Mr. Gunn who confirmed that IPLEX had been withdrawn from the market. Mr. Gunn also indicated that he would call Dr. Moxley to see if is was possible to enroll Mrs. Cacchillo in future clinical trials of IPLEX. Id. ¶ 18.[16] Dr. Zhou testified that she had no further discussions with Dr. Moxley or Mr. Gunn; that prior to her deposition on May 15, 2012, she had never heard the term "compassionate use;" and that if Plaintiff had indicated that she was looking for compassionate use of IPLEX she thinks she would have indicated that in her office notes, but she did not. Id. ¶ 20.

g. Potential Participation in a Phase IIB Trial

On August 10, 2007, the Cacchillos learned that there would be further studies of IPLEX in the treatment of MMD1 (the "Phase IIB Trial") from an announcement Insmed posted on the Muscular Dystrophy Association's ("MDA") website. The announcement indicated that recruitment for the Phase IIB Trial would begin in the near future. PSOF ¶ 36. At this point, Mr. Gunn had not called Plaintiff, had not sent her any information, had not checked in on her to see if she had applied for the clinical trial, and had not sent information about her to anyone to help enroll her in the Phase IIB Trial. Id. ¶¶ 23-24.[17] Mr. Cacchillo called Insmed and talked to Insmed's spokesperson, Baxter Phillips III, to ask him about the particulars of the upcoming trial. DSOF ¶ 25. Mr. Phillips could not

[16]Ronald Gunn left Insmed at the end of 2007. At his deposition, he did not recall a conversation with Dr. Zhou. Neither Plaintiff nor her husband witnessed the conversation between Dr. Zhou and Mr. Gunn. DSOF ¶ 21.

[17]Plaintiff contends that Mr. Gunn called Dr. Moxley to try to enroll Plaintiff in the Phase IIB trial, AC 122-23, but fails to provide sufficient support for this contention.

provide any particulars, id., but when Mr. Cacchillo asked Phillips whether he thought IPLEX would work for MMD1 patients, Phillips responded: "You better believe it will" and cited promising results from a test in Greece. RC pp. 78-79.

In September 2007, Mr. Cacchillo was getting "panicky" because he had not heard anything further about the Phase IIB Trial, DSOF ¶ 26, so he called Mr. Gunn. Mr. Gunn's voice mail message directed possible MMD1 trial subjects to call Insmed's Clinical Research and Study Manager Christine O'Neal.[18] Mr. Cacchillo then called Ms. O'Neal and left a message. Id. Ms. O'Neal returned Mr. Cacchillo's call on September 13, 2007. Id. ¶ 27. According to the Cacchillos (who both participated in the call via speaker phone), Ms. O'Neal confirmed that Plaintiff was on the list for consideration for the upcoming trial and indicated that she would send Dr. Zhou forms to fill out.[19] RC p. 131. However, Ms. O'Neal told them that Plaintiff would have to wait until trial sites were announced before Plaintiff could formally apply. Id. During the call, Mr. Cacchillo told Ms. O'Neal about a pamphlet they received at the MDA clinic in Albany, New York called "Volunteering for a Clinical Trial." He advised that the pamphlet contained a statement indicating that "for a serious illness, a pharmaceutical company might continue to provide the study medication to those patients who are responding well." DSOF ¶¶ 30-31. Ms. O'Neal responded: "Yes, pharmaceutical companies generally do that." R. C. p. 132. Ms. O'Neal did not say, however, that Insmed would provide IPLEX to Phase IIB trial participants after the trial. DSOF ¶ 34.

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[18]Ms. O'Neal left Insmed in June 2009.

[19]Ms. O'Neal does not recall speaking to the Cacchillos. DSOF ¶ 29.

h. Plaintiff Applies for a Phase IIB Trial

In late December 2008, Insmed announced on its website and through the website of the MDA that it had commenced recruitment for the Phase IIB Trial. RC pp. 190-91; Ex 38. The announcement read as follows:

> Insmed is developing [IPLEX] . . . , which has shown promising results in an open-label study in patients with myotonic dystrophy (DMI). To further our understanding of the effects of [IPLEX], we are conducting a randomized, placebo-controlled, double-blind clinical study in 60 patients with DMI....
>
> For more information about the study, please contact Insmed at clinicaltrials@Insmed.com. Or by Phone at 804-565-3130.

Ex 38.[20]

On January 2, 2008, Plaintiff called Ms. O'Neal "to inform her that [she] was very interested in participating" in the Phase IIB Trial, and that she was interested in two potential trial sites, URMC and Ohio State University ("OSU"). DSOF ¶ 42. Ms. O'Neal told Plaintiff that she could apply at both sites. Id. ¶ 43. Plaintiff asserts that Ms. O'Neal urged her to apply to both sites so that Plaintiff would be assured of getting into one. AC p. 129. There was no discussion of compassionate use during the call. DSOF ¶ 44. After the call, the Cacchillos never again spoke to Ms. O'Neal. Id. ¶ 45.

The Cacchillos then called the URMC but learned that site was already full. DSOF ¶ 46. They next called the OSU trial site, but were told that OSU had not yet received Institutional Review Board ("IRB") approval as a clinical trial site for the Phase IIB Trial, and were told to call back in February 2008. Id. ¶ 47. The Cacchillos sent a letter to OSU

[20] A double-blind study is one in which neither the investigator (í.e., physician in charge of the study at a given site) nor the patient knows whether the patient is receiving the active drug or a placebo. A placebo-controlled study is one in which a patient may receive one of two articles--the active drug in a uniform dosage or a placebo.

regarding Ms. Cacchillo's interests in participating in the trial. The letter says nothing about compassionate use. Id. ¶ 48.

Once the OSU site received approval, it began screening potential participants. The Chief Investigator of the Phase IIB Trial at OSU was Dr. John T. Kissel, the Sub-Investigator was Dr. Victoria Lawson, and the Clinical Research Coordinator was Amy Bartlett, an OSU employee. DSOF ¶ 49. The Cacchillos participated in a telephone call on March 24, 2008 with Dr. Lawson concerning Mrs. Cacchillo's possible participation in the Phase IIB Trial. Id. ¶ 51. Thereafter, Ms. Bartlett followed up by telephone with the Cacchillos and scheduled a screening visit. Id. ¶ 52. Ms. Bartlett testified that, during that call, the Cacchillos indicated their excitement about the Phase IIB Trial because there were not any other trials for MMD1, and thus they were willing to travel to OSU to be a part of it. Id. ¶ 53. Ms. Bartlett sent the Cacchillos a packet of materials to review, including the Research Subject Information and Consent Form ("OSU Consent Form"). Id. ¶ 54. Plaintiff was scheduled for a screening visit on April 7, 2008 at OSU. RC 132-33.

The OSU Consent Form named Insmed as the study sponsor; Dr. Kissel as the investigator; and Dr. Lawson as the sub-investigator. Def. Ex A-18. It explained the procedures and risks of the study; indicated that the sponsor would provide the "study drug;" and advised that information relative to each participant could be provided to the sponsor, various governmental bodies, various OSU bodies, and the Western Institutional Review Board. Id. The OSU Consent Form further provided that the sponsor would pay for the reasonable costs for necessary medical treatment caused by the product or procedures used in the study provided the treatment was not covered by the participant's medical insurance. Id. It also informed participants of the right to withdraw at any time; the

study doctor's right to end a participant's involvement in the study; and the sponsor's right to stop the study. Id. The OSU Consent Form directed subjects to "ask the study doctor or the study staff to explain any words or information that you do not clearly understand," and further directed subjects to contact Dr. Kissel or Sharon Chelnick (a study staff member) with any "questions, concerns or complaints about this study or your participation in the study or if at any time you feel you have experienced a research-related injury or a reaction to the study medication." Id. Finally, the OSC Consent Form informed subjects to direct any questions about their "rights as a research subject or if you have questions, concerns or complaints about the research," to the Western Institutional Review Board. Id.

On April 7, 2008, the Cacchillos traveled to OSU for a screening visit for the Phase IIB Trial. DSOF ¶ 55. Mr. Cacchillo testified that at the time, he and his wife "definitely" intended that she participate in the Phase IIB Trial if she was accepted. Id. ¶ 56. During the screening visit, Plaintiff underwent a physical examination by Dr. Lawson, and underwent various other tests and procedures. Id. ¶ 57. The Cacchillos did not ask Dr. Lawson what would happen after the trial, nor did they discuss long-term or compassionate use of IPLEX. DSOF ¶ 64.

The Cacchillos also met with Ms. Bartlett to go over the trial paperwork and to review and sign the OSU Consent form. Ms. Bartlett reviewed the journals and forms Plaintiff would have to complete throughout the course of the trial, all of which were provided by Insmed and bore Insmed's logo. At the end of their discussion with Ms. Bartlett, Mr. Cacchillo asked: "Amy, what happens after the trial if [Plaintiff] gets the drug and does well?" DSOF ¶ 59. Ms. Bartlett responded: "They will put her on compassionate

care." Id. ¶ 60.[21] The Cacchillos asked no follow-up questions and did not ask for any details. Id. ¶ 61. Mrs. Cacchillo testified that they were "quite familiar" with what compassionate use was all about, having read about it on the internet. Id. ¶ 62. Plaintiff knew at the time that Ms. Bartlett worked for OSU, but asserts that it was "apparent that she was representing Insmed ... [she] sounded like and behaved like she was an employee of Insmed." AC p. 77; see also RC pp. 193-194.[22]

Plaintiff signed the OSU Consent form at the end of the April 7, 2008 meeting. RC p. 149; Ex 18. Insmed reimbursed the Cacchillos for their travel costs and paid

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[21]During her deposition, Amy Bartlett testified that she could not recall her discussion with the Cacchillos at the screening visit, but did not believe she stated or implied that Insmed would put Mrs. Cacchillo on compassionate care at the conclusion of the trial. See Bartlett Tr. pp 72-77, 100. She did concede, however, that she might have mentioned that in another study, compassionate care was given. Id. pp. 74-76. She further testified that, if she was asked whether Plaintiff could stay on IPLEX at the conclusion of the trial, "I would -- definitely would have said that study's designed when it's done, data would be analyzed and then they decide from there where it's going to go, but we don't have anything, I can't say 'When it's done, you get the drug,' I have no authority in that." Id. p. 75. Ms. Bartlett also testified that she understood that she did not have authority to bind Insmed outside of the trial, did not have discretion to make decisions about how the trial would proceed, and does not believe that she gave the appearance that she had such authority. Bartlett Dep. pp. 93-94.

[22]During their depositions, the Cacchillos testified that they believed that Amy Bartlett represented Insmed due to, *inter alia,* the following factors:

-Amy Bartlett told them she didn't "see a problem with" the Cacchillos staying at a hotel that was $10 more expensive than the hotel approved by Insmed, (AC Tr. 77:24-79:3) and indicated that she would "contact Christine O'Neal and see if I can work it out and get [her] okay." (RC Tr. 201:13-202:3.);

-Ms. Bartlett told them "there should not be a problem" if Mrs. Cacchillo stopped at a casino on the trip home wearing her activity monitor, even though she would be sitting at a slot machine. (AC Tr. 79:4-80:12.)

-During the trial, the Cacchillos saw materials with the Insmed logo on it. (AC Tr. 80:13-23; RC Tr. 202:3-7, 205:4-22.)

-After agreeing to participate in the trial, Ms. Bartlett gave the Cacchillos an Insmed travel bag, ice chest, and cooler. (AC 225:2-226:7; RC 202:3-7.)

-Ms. Bartlett appeared to be in charge. (AC 225:8-226:7; RC 201:10-11, 204:15-205:3, 206:22-207:7.)

-OSU reported the data from the trial to Insmed, including information from Mrs. Cacchillo's step activity monitor. (RC 205:4-22, 206:5-17.)

directly for their hotel room while they were staying in Columbus for the screening visit, and continued to do so throughout the trial. At the time of Mrs. Cacchillo's enrollment in the study, Plaintiff understood that Insmed was the sponsor of the trial, but that the trial was being conducted by OSU. DSOF ¶ 68. The undisputed evidence indicates that no one from Insmed ever spoke about Ms. Bartlett to the Cacchillos. Id. ¶ 71.[23]

Plaintiff was aware when she enrolled in the study that she would not know whether she was being administered the placebo until after the trial was completed, and that there would be a period of months following her last dose of IPLEX when the drug would be unavailable while the results were being computed. Id. ¶ 74. Plaintiff was also of the opinion that if she was not progressing and was on a placebo, she would drop out. Id. ¶ 75. At the time, the Cacchillos were hoping there would be a Phase III trial of IPLEX and that Mrs. Cacchillo could participate in that as a means of continued IPLEX treatment beyond the six month period of the Phase IIB Trial. Id. ¶ 76.

i. Plaintiff's Participation in the Phase IIB Trial

During the Phase IIB trial, patients were randomly assigned to either the control group or drug group, and only two individuals at Insmed - Kristine Goacher, who performed the randomization, and David Green, Insmed's pharmacist - were unblinded. Def. Response to PSOF ¶ 52. Trial site investigators and patients were blinded. Id. Insmed controlled patients' IPLEX dosage and prepackaged it at Insmed's Boulder, Colorado facility in vials which bore Insmed's name, for individual patients before shipping it to trial sites. Id. ¶ 56. Mrs. Cacchillo received IPLEX from May 2008 through October

[23]The contract between Insmed and OSU indicates that the relationship of OSU, the principal investigator and its personnel, to Insmed was that of an independent contractor. DSOF ¶ 72. However, there is no evidence that Plaintiff was aware of this fact at the time.

2008. DSOF ¶ 77.[24] Insmed regularly audited the trial site to ensure that protocol was being followed. PSOF ¶ 55. Insmed created the paperwork that was used during the trial by subjects and investigators, nearly all of which bore Insmed's logo.

Over the course of the trial, Plaintiff made eight (8) visits to OSU. PSOF ¶ 58. The journey from Plaintiff's home in Schenectady, New York and Columbus, Ohio was twelve hundred (1,200) miles. Id. ¶ 57. The trips, and the tests performed while Plaintiff was at the test site, were physically taxing and painful.[25] In addition, Plaintiff was required to wear a step activity monitor around her ankle for a number of eight (8) day periods during the trial. This monitored her physical activity while she was at home. AC p. 79. Plaintiff was also required to record her activities on a daily basis in a journal provided by Insmed and that bore Insmed's logo on each page. Further, Plaintiff was required to administer an injection of IPLEX each day, all of which she did faithfully. AC pp. 79, 86; PSOF ¶¶ 59-60.[26]

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[24]During the Phase IIB Trial, Plaintiff used 1.1 ml per day of IPLEX, which was a little over one vial, and received 90 vials a month. DSOF ¶ 185.

[25]Due to MMD1's attack on Plaintiff's neuromuscular system, using rest stop bathrooms during these trips was dangerous and difficult for her because of slippery floors or because, if a toilet was too low, she could not lift herself up once she had sat down. RC p. 48. Mrs. Cacchillo also suffers pain as a result of prolonged sitting, RC p. 21, making the long car rides difficult.

Plaintiff contends that trial visits involved days of stressful and painful tests and examinations. During these she had to undergo a muscle strength test in which her limbs were stretched as far as possible in a series of ways causing her lasting and significant pain. She also had to take a glucose tolerance test, which required that she break a ten (10) hour fast with an extremely sugary drink so that four (4) blood samples measuring the resultant spike in her blood sugar could be taken over the course of two (2) hours. Also during every visit, numerous blood samples were taken from Plaintiff and she was made to undergo exhausting tests such as walking for six (6) minutes unaided twice during one session, walking thirty (30) feet, or climbing stairs as quickly as possible. She also took cognitive tests on sheets of paper bearing Insmed's logo.

[26]Plaintiff also notes that in June 2008, her mother passed away and the funeral was scheduled for a day when Plaintiff had a scheduled trial visit. RC p. 203 . She prevailed upon her family to delay the funeral two (2) weeks so that she could fulfill her trial obligations. Id.

j. Plaintiff's Improvement While Taking IPLEX

In the six (6) months Plaintiff participated in the trial, she observed substantial improvements in her endurance, muscle mass, levels of pain, and dexterity.[27] Plaintiff also contends that she improved in twenty-nine (29) of the thirty-nine (39) endpoints measured by the MMD1 trial, and either held ground or declined insignificantly in the remaining ten (10).

Plaintiff's subjective improvements were corroborated by her physicians and OSU personnel. Dr. Lawson noted that, although she was "uncompelled" by Plaintiff's trial results, Plaintiff "looked like she had improved with respect to either muscle bulk or weight, that she appeared more filled out, healthier appearing," Lawson Dep. p. 35, and appeared to have improved in areas of posture, endurance, levels of pain, and dexterity. Id. pp. 32-33.[28] Ms. Bartlett felt that "[t]here were noticeable positive changes that were observed

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[27]At the beginning of the trial, Plaintiff needed a wheelchair if she was expected to walk long distances, and by the end she was able to walk those distances on her own. AC pp. 97-98. Prior to the trial she needed a walker in order to walk any distance, and by the end she "would use the walker in [rest stop] restrooms for safety only." Id. p. 98. While she still availed herself of her husband's arm when walking, she held it "lightly as you would hold your husband's arm, just not because you needed it, but just [to] give me security" and did not cling to it as she had before. Id. When cleaning around the house at the end of the trial, she was able to do more than twice as much as she had been able to do prior to the IPLEX treatment in "less time [with] less rest needed." Id. p. 100. At the end of the trial, Plaintiff could spend a day shopping, including trying on clothes without assistance, whereas she could only have managed going to one store prior to taking IPLEX and could not manipulate buttons or zippers so as to try on new clothes. Id. Before taking IPLEX, showering would take between "forty-five (45) minutes to an hour," whereas at the end of the trial showering took only twenty (20) to thirty (30) minutes. Id. p. 101. Plaintiff could use tweezers at the end of her IPLEX treatment whereas she could not do so before the trial, id. p. 202, and she experienced much less pain as a result of taking IPLEX. Id. p. 2l2. She also no longer needed a neck brace to keep her head up at the end of the trial and it was easier for her to sit up. By September 2008, the Cacchillos were making plans to spend the winter in Florida, something Plaintiff had not been able to manage since 2006. RC p. 36.

[28]Dr. Lawson testified:

> I saw indicators of improvement that are more difficult to capture in a specific test. Things like posture, her posture was more erect; expressions of discomfort, she seemed to have less pain; she used devices that she would use to improve comfort and a specific example is she would use a back brace when she was performing a walk test, she seemed to use that less;

(continued...)

while [Mrs. Cacchillo] participated in the study." Bartlett Dep. p. 32. The step activity monitor device noted an increase in Plaintiff's daily activity and showed, according to Ms. Bartlett, "that Angela had much more energy, which she also reported in her evaluations, and she was able to do things at a much higher level in 6 months time." Id. Ms. Bartlett stated that "[u]nfortunately, many of [Plaintiff's improvements] were not able to be measured by the study" trial data and tests. Id.

k. Plaintiff's Request for Continuation of IPLEX Post-Trial

Toward the end of the trial the Cacchillos began to voice that they were interested in continuing on IPLEX and asked Dr. Lawson what opportunities there might be. DSOF ¶ 78. Dr. Lawson's initial response was neutral because she had no idea if there would be a Phase III Trial or whether Insmed would be in a position to provide compassionate use. Id. ¶ 79. Dr. Lawson emailed Insmed concerning the time frame for when it would unblind the treatment groups, and asked whether Insmed would "have any sort of Compassionate Use or open-label study that subjects from [the Phase IIB] study could roll into?" DSOF ¶ 82. Dr. Lawson did not mention Plaintiff or request that Insmed support a compassionate use application for Plaintiff. Id. ¶ 83.

In September 2008, Ms. Bartlett contacted Brock Holst, Insmed's Site Monitor assigned to OSU, and asked about keeping Plaintiff on IPLEX. Bartlett Dep. p. 103; RC p. 227; Lawson Dep. p. 73. Ms. Bartlett contends that at the time she had no idea whether

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[28](...continued)
her ease of movement seemed to be improved; her reliance on her husband seemed to be less; she seemed less fatigued in generally.

Lawson Dep. pp. 32-33.

Plaintiff would be able to continue on IPLEX after the trial. See Bartlett Dep. pp. 100-01.[29]

On November 3, 2008, Mr. Holst responded, indicating that there would be no "Compassionate Use or open-label study that subjects from this phase 2 study could roll into" but that continued access to IPLEX could be secured through the next phase of the study, should it go forward. Lawson Dep. p. 76-77. This was communicated to the Cacchillos who, given Plaintiff's improvement and what they thought were the positive results of the prior MMD 1 trial phases, were confident that a Phase III Trial would begin shortly. AC p. 161; RC p. 67, 255.

I. January 2009

By January 2009, Plaintiff's physical condition had deteriorated significantly. RC p. 158. On January 12, 2009, Plaintiff sent Dr. Lawson and Ms. Bartlett an email updating them on her situation. In the email, Mrs. Cacchillo indicated that she was "encouraged by the prospect of a Phase III trial and the possibility of my inclusion in it. I am hopeful that Phase III will begin before August 1, 2009 as I will then be 66 years old which may exclude me." Id. ¶ 85. Mrs. Cacchillo further indicated that she was "grateful for the wonderful opportunity afforded me by Ohio State and Insmed to participate in Phase II and would

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[29]On October 20, 2008, during Plaintiff's last visit to OSU, the Cacchillo's mentioned to Ms. Bartlett their belief that Plaintiff would receive IPLEX when her trial participation ended. Ms. Bartlett testified:

> It seemed like [Mr. Cacchillo] thought that's what was going to happen. I was kind of surprised. And I remember sitting there . . . like looking confused, like why would you even say that? ... I just remember he said, "Well, I just can't wait till it's done and then we can get the drug and everything." And I was like, "Well, they've got to analyze the data and everything and then we'll see where things go. It's going to take a while." And I remember he was like, "Well, then you said we could get the drug." And I was like — "because she's gotten better." And I remember being like "no. That's not something that I — no."

Bartlett Dep. pp. 100-01.

like to be part of a future Phase III." Id. ¶ 86. At this point in time, Plaintiff had not yet received formal confirmation whether she had been on IPLEX or a placebo. AC pp. 87, 106; RC p. 159.

m. February 12, 2009 Press Release

By February of 2009, the Cacchillos were getting "panicky" because they had not heard anything about the results of the Phase IIB Trial or a future Phase III trial, and were worried that Plaintiff would be too old to participate in a Phase III trial because she turned 66 in August 2009. DSOF ¶ 88. The Cacchillos went to Insmed's website and printed what they saw there because, at that point, "compassionate use was [Mrs. Cacchillo's] way of — of continuing on the drug." AC p. 155. On February 21, 2009, Mr. Cacchillo attempted to print a copy of a February 12, 2009 press release from Insmed's website discussing the investigational availability of IPLEX. DSOF ¶ 91. Mr. Cacchillo testified that the second page would not print out, and therefore he copied the web page "verbatim." Id. ¶ 92. According to Plaintiff, the February 12, 2009 press release addressed IPLEX and contained Insmed's promise of supporting compassionate use, the same as was made in August 2007. R. Cacchillo 12/17/10 Aff., ¶ 8; See Def. Ex. 14;[30] but see

[30]The first page, which is the printout obtained by Plaintiff's husband, starts with a paragraph providing a short background of the use of the drug in the phase II study for MMD1, the expanded access program for amyotrophic lateral sclerosis (ALS) in Italy, and for early stage research programs investigating retinopathy of prematurity (ROP) and HIV Adipose Redistribution Syndrome (HARS).

The second paragraph addresses IPLEX in association with MMD1. This indicates that Insmed "is conducting a randomized, placebo-controlled, double-blind clinical study in 60 patients with MMD." The paragraph concludes by stating: "Patients will undergo assessments to determine the effect of IPLEX on muscular strength, endurance, ambulation, cognitive functioning, gastrointestinal symptoms, and general health status." Def. Ex. 14.

The next four paragraphs address IPLEX's use in connection with ALS. The last sentence states: "Regarding the availability of IPLEX in the United States, Insmed has issued the following statement:" Immediately following this is the subheading "Commercial Availability." This is followed by a sentence stating: (continued...)

DSOF ¶¶ 162-74.[31]

Upon seeing this information, Mr. Cacchillo "was excited that there may be an avenue for [his wife's] treatment," RC p. 161, and in fact was so "excited" to see the information there that he wrote at the top of the printed page: "Process for applying for MMD1, IPLEX compassionate use." RC p. 160. Mr. Cacchillo, who was "all psyched up"

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[30](...continued)
"IPLEX is not commercially available; and, therefore, Insmed cannot fill any prescription written for IPLEX. Although it is an approved drug, it has been moved to FDA's 'discontinued' status, and Insmed has ceased commercial distribution of the product." Following this, on the very bottom of the printed page, is another subheading entitled "Investigational Availability."

The next page consists of the handwriting of Plaintiff's husband and starts with an underlined subheading entitled "Investigational Availability Continued." This is followed by the phrase "compassionate use" in parentheses, and then explains that:

> Insmed has discussed regulatory alternatives with the FDA[.] Investigational drugs such as IPLEX can be accessed by patients through controlled methods allowed under the US regulations[.] "A treatment IND" or "a single patient IND[.]" A treatment IND is a regulatory pathway that allow investigational drugs to be distributed to patients after clinical trials have been conducted with the drug but before FDA approval has been granted for its use. A treatment IND is subject to strict conditions and oversight. Alternatively, a physician may submit a IND application to [the] FDA for the treatment of an individual patient under a single patient IND. Sometimes known as 'compassionate use,' the process for applying for a single patient IND is outlined at HTTP://www.FDA.gov/cder/cancer/ singleIND.htm.".

Def. Ex. 14. (emphasis in handwritten copy).

The third page, also in Plaintiff's husband's handwriting, states as follows:

> Should a physician decide to seek IPLEX for the treatment of a patient, he or she should contact Insmed. Insmed will provide a drug supply reference statement that acknowledges Insmed's commitment to the requesting physician. Single patient IND applications would then be submitted to the division of neurology products at the FDA for consideration. Patients or physician inquiries regarding IPLEX should be directed to concal@Insmed.com."

Def. Ex. 14.

[31]Defendant contends that the website posting that Mr. Cacchillo viewed in 2009 was related to the investigational availability of IPLEX in the United States for ALS patients as allowed by the FDA, and that Mr. Cacchillo's copying of the web posting missed the "liberal references to ALS." See DSOF ¶¶ 162-74. Plaintiff does not agree and believes that the language of the web page transcribed by Mr. Cacchillo on February 21, 2009 committed Insmed to providing support of the compassionate use application of any individual with a serious illness. DSOF ¶ 97. Plaintiff never discussed the website's contents with anyone at Insmed. Id. ¶ 100. Plaintiff does not recall reviewing the website on February 21, 2009, did not compare what was actually on the webpage with Mr. Cacchillo's handwritten notes, and did not know whether Mr. Cacchillo omitted from his hand-written notes any references to ALS in the text. Id. ¶¶ 101-103.

upon seeing this information, told his wife: "Ange, you don't have to worry. If the trial — if phase III doesn't come, we can get compassionate use." RC pp. 158-159. Mr. Cacchillo testified that his response at the time was: "Look what I found, there's — there's hope." RC p. 161. Mr. Cacchillo contends that the information in the press release was the same as he saw in August 2007. RC p. 162-65.

n. Insmed's Decision Regarding a Phase III MMD1 Trial/Plaintiff's Request for Compassionate Use

On June 29, 2009, the Cacchillos learned that Insmed was unconvinced by the MMD1 trial data and was terminating the MMD1 study.[32] RC 227. Shortly thereafter, OSU was told by Insmed that Plaintiff had been on IPLEX and not a placebo. By letter dated July 14, 2009, Dr. Kissel, Dr. Lawson, and Ms. Bartlett informed Plaintiff that she had been assigned IPLEX during the trial. DSOF ¶ 110. On the same day, Ms. Bartlett sent an email to Leigh Haynes, then a Clinical Research Associate at Insmed, copying Dr. Lawson, stating:

> Dr. Lawson and Dr. Kissel wanted me to ask we had one patient who thought she did very well on the drug and we thought it might be placebo effect but now we can see she was on the medicine and she did do much better on it. Did you guys see that nationally with any cases and are you making special allowances for those individuals to still receive the drug? It was for patient 3802AJC. Thanks— Amy.

DSOF ¶ 112.

Ms. Haynes forwarded Ms. Bartlett's email to Anne Smith, who served as Director of Clinical Research at Insmed. Id. ¶ 113. Ms. Smith did not interpret Ms. Bartlett's email as a request to support a single patient IND sponsored by one of Mrs.

[32]Dr. Kissel testified that the results were disappointing but not surprising to him since there seemed to be little if any improvement among the OSU subjects. Kissel Dep. p. 60-61.

Cacchillo's physicians. Id. ¶ 114. Rather, Ms. Smith understood Ms. Bartlett's email to be an inquiry into whether Insmed had any plans to continue MMD1 trial participants on IPLEX. Id. ¶ 115. Ms. Smith responded to Ms. Haynes's email on July 17, 2009, and provided her with proposed language for Ms. Haynes's response to Ms. Bartlett. Id. ¶ 116.

On July 27, 2009, Insmed announced that it was immediately ceasing the supply of IPLEX to any new patients, and that it would not be initiating any further clinical trials of IPLEX at that time.[33] DSOF ¶ 122; PSOF ¶ 66.

On July 29, 2009, Ms. Haynes responded to Ms. Bartlett's email, stating:

> I apologize for not responding to you earlier. Unfortunately the trial design does not allow for open label extension use and the regulations would not allow us to set up a treatment IND without positive phase 2 results, therefore we don't have a mechanism to provide IPLEX to myotonic dystrophy patients at this time.

DSOF ¶ 117.[34] Neither Ms. Bartlett or Dr. Lawson followed up with Insmed in any manner with respect to Insmed's response. Id. ¶ 120.

Also on July 29, 2009, the Cacchillos sent an email to Ms. Bartlett stating:

> Much thanks to you and Drs. Lawson and Kissel that we beat that July 27th deadline. In a similar situation that occurred this year, a precedent was set, in which 16 U.S. ALS patients were granted Single Patient INDS (Compassionate Care) by both Insmed and the FDA if they met a March 6th deadline (see document, FDA Position On Allowing Patients With ALS Access To IPLEX under an IND). Since March, 4 out of the 16 have dropped out of the IPLEX ALS IND program. Consequently, there should be enough IPLEX to treat me. I am also mailing a copy of a letter that I sent to

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[33]In March 2009, Insmed represented to the FDA that it would conduct a clinical trial of IPLEX for the treatment of ALS. See Pl. Response to DSOF ¶ 122.

[34]Open-label extension use refers to a mechanism at the end of a blinded, placebo controlled trial in which study participants could receive the treatment drug, and know that they were receiving the treatment drug, for some period of time after the initial phase of the trial concluded. DSOF ¶ 118. A treatment IND is defined in the Code of Federal Regulations, and is initiated and managed by the drug company where there is evidence of drug efficacy and the drug company is actively developing the drug. Id. ¶ 119.

> Leigh Haynes, Clinical Research Associate at Insmed requesting that they honor your request for Compassionate Care. I truly appreciate your help! Angela

DSOF ¶ 123.

The Cacchillos also sent Dr. Lawson an email on July 29, 2009 indicating that they had spoken to Ms. Bartlett and had learned that Dr. Lawson and Ms. Bartlett had requested compassionate care for her from Insmed. The email further indicates that Plaintiff had intended to ask Dr. Lawson to file a petition for compassionate care at her next appointment, and enclosed certain documents that she thought could be of help in dealing with Insmed or the FDA. DSOF ¶ 126. Dr. Lawson responded on July 31, 2009, indicating that she "was just not sure if the FDA or company will budge." Id. ¶ 127. When asked what she meant by this statement, Dr. Lawson testified that she did not think the FDA would approve a compassionate use application with negative phase II results and where the drug was no longer being produced, but she was not sure of this because she had not previously put in a compassionate use application. Lawson Dep. pp 86-87.[35]

Mrs. Cacchillo also wrote a letter to Ms. Haynes on July 29, 2009 advising of what Plaintiff considered her success using IPLEX, and asked that Dr. Kissel, Dr. Lawson, and Ms. Bartlett's request for companionate care for her be honored because it preceded Insmed's announcement that it would no longer provide IPLEX to new patients. See AC Ex. 21. Insmed did not have a policy with respect to compassionate use requests from MMD1 patients. DSOF ¶ 138. Rather, such requests were handled on a case-by-case

[35]Dr. Kissel similarly testified that he did not think the FDA would grant a Phase IIB Trial participant compassionate use in light of the negative trial results and the fact that IPLEX was no longer manufactured. Kissel Dep. pp. 57- 58. Dr. Kissel also testified that he had not seen the criteria by which the FDA judges compassionate use applications. Id. p. 66.

basis. Id. ¶ 139. By letter dated August 6, 2009, Glen Kelley, formerly Insmed's President of Regulatory Affairs, wrote to Mrs. Cacchillo:

> Unfortunately we are unable to grant your request for compassionate use of IPLEX due to the fact that the clinical trial design for the study in which you participated does not allow for open label extension use (compassionate use)
>
> .... Unfortunately, at this time, there is no mechanism for Insmed to provide IPLEX to you outside a clinical trial.

PSOF ¶ 68.[36]

No one from OSU followed up with Mr. Kelley regarding his August 6, 2009 letter. DSOF ¶ 140. Subsequently, the Cacchillos requested that Ms. Bartlett provide them with evidence that suggested that Plaintiff improved during the clinical trial. Id. ¶ 141. Ms. Bartlett testified that she reviewed the data and the only apparently positive data collected was the results from Mrs. Cacchillo's step activity monitor. Id. ¶ 142; see PSOF ¶ 61.[37] Bartlett also testified, however, that she is not a physician or nurse, has no medical

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[36]Mr. Kelley testified that he understood the term "compassionate use" to be an umbrella term covering a variety of mechanisms such as open-label use, and was not limited to a single-patient IND. DSOF ¶ 132. Mr. Kelley further testified that he did not recall any discussions that would have constituted a blanket decision regarding compassionate use with respect to Phase IIB Trial patients, but that the negative results from the trial would be a very heavy negative factor weighing against compassionate use. Id. ¶ 133.

Ms. Smith testified that she reviewed Mr. Kelley's letter to Plaintiff, and that the letter did not discuss a single-patient IND because "the understanding was that she was looking at Insmed to do something." Id. ¶ 134. Ms. Smith testified that, had Insmed been asked at the time whether it would supply Plaintiff with IPLEX through a single-patient IND, then Insmed would have to consider several factors, including the fact that IPLEX was not effective in MMD1. Id. ¶ 135. Ms. Smith further testified that "[a]necdotal reports from patients are subject to bias" and therefore Mrs. Cacchillo's beliefs about her improvement would not have mattered in determining whether to support a single-patient IND sponsored by a physician. Id. ¶ 136. Ms. Smith testified that she believes the term "compassionate use" is "a vague term bandied about to mean different things by different people" but "would involve a manufacturer or a company involvement in providing the drug[, w]hereas a single-patient IND requires initiative on an investigator or doctor's part." Id. ¶ 137.

[37](According to Ms. Bartlett, Plaintiff's step activity monitor indicated that Plaintiff "had much more energy, which she also reported in her evaluations, and she was able to do things at a much higher level in 6 months time" at the end of her trial participation.)

training, and is not qualified to determine whether the results of the step activity monitor actually show improvement. DSOF ¶ 143; see also Bartlett Dep. pp. 31-32, 117-19.

Mrs. Cacchillo returned to OSU on October 7, 2009 to meet with Dr. Lawson and go over her study results. DSOF ¶ 144.[38] Dr. Lawson testified that she did not know whether Mrs. Cacchillo would have continued to improve if she had continued taking IPLEX, and that it is possible that Mrs. Cacchillo experienced a placebo effect during the Phase IIB Trial. Id. ¶¶ 148-49. However, Dr. Lawson also testified that "as [Plaintiff's] physician I'd like to see her continue on IPLEX" and would sponsor Mrs. Cacchillo's compassionate use application if Insmed would support it. Larson Dep. p. 58.

o. Production of IPLEX

Insmed produced IPLEX at a facility it owned in Boulder, Colorado between April 2004 and March 31, 2009. PSOF ¶ 14. On March 31, 2009, Insmed sold the Boulder facility to Merck & Co., Inc. for one hundred and thirty million dollars ($130,000,000.00). Id. ¶ 15. Prior to purchasing the Boulder, Colorado facility, IPLEX was produced on a small scale "run-by-run basis" through a third party. Id. ¶ 16. Insmed depleted its supply of IPLEX on December 11, 2011. DSOF ¶ 177. Insmed does not currently own or lease a manufacturing facility that could manufacture IPLEX, nor does it currently contract with any third parties that could manufacture IPLEX. Id. ¶ 178. If Insmed were to resume the production of a clinical trial amount of IPLEX through a third party, the cost is estimated at between $10 and $16.2 million. See Def. Response to PSOF, ¶ 17. If Insmed were to construct a facility to manufacture IPLEX, it would take about 18 to 24 months to build,

[38]After the trial, Plaintiff continued as a patient of Dr. Lawson. DSOF ¶ 147.

and the cost to construct it would be anywhere from $20 to $220 million. DSOF ¶ 181.

IV. DISCUSSION

a. Breach of Contract

Under New York law,[39] to establish a triable breach of contract claim Plaintiff must set forth evidence of: 1) the existence of a contract between the parties; 2) adequate performance of that contract by Plaintiff; 3) breach of the contract by Defendant; and 4) damages. Eternity Global Master Fund Ltd. Morgan Guar. Trust Co. of N.Y., 375 F.3d 168, 177 (2d Cir. 2004).

1. Existence of a Contract

Proof of the existence of a contract requires proof of an "offer, acceptance, consideration, mutual assent and intent to be bound" by the parties. Leibowitz v. Cornell Univ., 584 F.3d 487, 507 (2d Cir. 2009). A contract may be expressed or implied. An express contract is one derived by "declared intention." Brown v. St. Paul Travelers Co., 331 Fed. Appx. 68, 70 (2d Cir. 2009). "Under New York law, the conduct of the parties may lead to the inference of a binding agreement: A contract implied in fact may result as an inference from the facts and circumstances of the case, although not formally stated in words, and is derived from the presumed intention of the parties as indicated by their conduct. It is just as binding as an express contract arising from declared intention, since in the law there is no distinction between agreements made by words and those made by conduct." Brown v. St. Paul Travelers Co., 331 Fed. Appx. 68, 70 (2d Cir. 2009)(citing

[39]Because both parties have relied on New York law in their memoranda of law, they have implicitly consented to the application of New York law. This "'implied consent ... is sufficient to establish choice of law.'" Krumme v. WestPoint Stevens Inc., 238 F.3d 133, 138 (2d Cir. 2000) (quoting Tehran–Berkeley Civil & Envtl. Eng'rs v. Tippetts–Abbett–McCarthy–Stratton, 888 F.2d 239, 242 (2d Cir.1989)).

Beth Israel Med. Ctr. v. Horizon Blue Cross & Blue Shield of N.J., Inc., 448 F.3d 573, 582 (2d Cir. 2006) & Jemzura v. Jemzura, 330 N.E.2d 414, 419-420 (1975))(interior quotation marks omitted); see Nadel v. Play-By-Play Toys & Novelties, Inc., 208 F.3d 368, 377 (2d Cir. 2000).[40]

"[A]ll the terms contemplated by [an] agreement need not be fixed with complete and perfect certainty for a contract to have legal efficacy," although a contract lacking "essential terms" may be "too indefinite [and] no legally enforceable contract will result." V'Soske v.Barwick, 404 F.2d 495, 500 (2d Cir. 1968). Whether a contract contains essential terms depends upon the "subject of the agreement, its complexity, the purpose for which the contract was made, the circumstances under which it was made, and the relation of the parties." Cobble Hill Nursing Home, Inc. v. Henry & Warren Corp., 74 N.Y.2d 475, 482-83 (1989). Of course,

> [i]t is a basic principle of contract law that the unilateral understandings of one party, no matter how subjectively reasonable, are insufficient to form the basis of a contractual promise. Di Giulio v. City of Buffalo, 237 A.D.2d 938, 939, 655 N.Y.S.2d 215, 217 (4th Dep't 1997). To have a valid, enforceable contractual obligation, there must be a meeting of the minds. I.G. Second Generation Partners, L.P. v. Duane Reade, 17 A.D.3d 206, 793 N.Y.S.2d 379, 382 (1st Dep't 2005).

Suthers v. Amgen, Inc., 372 F. Supp.2d 416, 424 (S.D.N.Y. 2005).

Assuming, arguendo, that statements by Christine O'Neal, Amy Bartlett, and Insmed through its website and postings on the Muscular Dystrophy Association's website, either alone or in combination, could be construed as "an offer" by Insmed to provide Plaintiff with IPLEX after her participation in the Phase II clinical trial, see Restatement

[40](In the case of an implied contract, the elements of a contract "may be inferred from the facts and circumstances of each case.")

Contracts, 2d §24;[41] Arbor Hill Concerned Citizens Neighborhood Ass'n v. County of Albany, 369 F.3d 91, 95 (2d Cir. 2004), the terms of the purported agreement were not definite enough to constitute an enforceable promise. Plaintiff contends that "Insmed's offer was that if Mrs. Cacchillo performed her obligations as a trial subject and did well on IPLEX, Insmed would provide her with IPLEX treatment at the end of the trial." Pl. MOL, p. 30. In this regard, Plaintiff asserts that the agreement was that Insmed would supply IPLEX "until a better treatment is found, the patient passes away, the treatment stops working, or the patient is cured." Id. However, even as understood by Plaintiff, the terms of the putative agreement were not definite enough to constitute a binding agreement. The duration of Defendant's purported obligation was unclear, and does not constitute a definite enough term to support a legally binding agreement. No reasonable fact finder could find that an agreement was reached on this essential term.

Moreover, the means by which Insmed would supply the IPLEX to Plaintiff pursuant to this putative agreement was also uncertain. According to Plaintiff, the IPLEX would be provided to her "by one of three (3) paths; 1) through a [phase III] clinical trial, 2) compassionate use, or 3) normal channels upon mass market approval of the drug." Id. Plaintiff argues that because the Phase IIB Trial in which Plaintiff participated had not been completed at the time the purported offer was made, "Insmed could not [have been] expected to commit to any one path as it needed to account for future events (*i.e*. delays in FDA approval . . .)." Id. But the argument begs the conclusion - that is, at the time Plaintiff entered the Phase IIB Trial (which is the point in time when the purported

[41]An offer is a "manifestation of a willingness to enter into a bargain, so made as to justify another person in understanding that his assent to that bargain is invited and will conclude it."

agreement was supposedly entered), the means of providing the drug was so uncertain that there could not have been a bilateral meeting of the minds on this essential term. There was no certainty that Plaintiff would be assigned IPLEX (as opposed to a placebo) or that she would do well on it; it was unknown whether the Phase IIB Trial would be successful enough to warrant a Phase III trial or support a treatment IND; it was unknown whether a physician would come forward to support an individual IND for Plaintiff (if she received IPLEX and did well on it); and it was uncertain that the drug would be approved by the FDA for treatment of MMD1. Given these uncertainties, no reasonable fact finder could conclude that the means of Insmed's obligation was specific enough to form a binding agreement.

There are insufficient facts indicating an agreement between Plaintiff and Defendant that, no matter the results of the trial, Plaintiff would receive IPLEX after the clinical trial. Plaintiff's unilateral understanding of the situation is insufficient to form the basis of an agreement.

2. Statute of Frauds

The putative contract is also barred by the New York Statute of Frauds requirement that an agreement that cannot be performed within one year or before the end of a lifetime must be memorialized in a writing. See NY GOL §5-701(a)(1).[42] In determining "whether a

[42]This provides:

a. Every agreement, promise or undertaking is void, unless it or some note or memorandum thereof be in writing, and subscribed by the party to be charged therewith, or by his lawful agent, if such agreement, promise or undertaking:

1. By its terms is not to be performed within one year from the making thereof or the performance of which is not to be completed before the end of a lifetime.

(continued...)

contract is capable of performance within a year for Statute of Frauds purposes, the endurance of defendant's liability is the deciding factor." Levine v. Zadro Prods., Inc., 2003 WL 21344550, at *4 (S.D.N.Y. June 9, 2003)(internal quotation marks and alteration omitted). "In order to remove an agreement from the application of the statute of frauds, both parties must be able to complete their performance of the contract within one year." Sheehy v. Clifford Chance Rogers & Wells LLP, 3 N.Y.3d 554, 560 (2004).

Unlike an agreement to support Plaintiff's compassionate use application,[43] the putative agreement to supply Plaintiff with IPLEX "until a better treatment is found, the patient passes away, the treatment stops working, or the patient is cured," Pl. MOL p. 30, is open ended and necessarily implicates a term of over a year before Defendant could complete its obligation. Indeed, in light of Plaintiff's arguments that [MMD1] is incurable, that there is no alternative FDA approved treatment available, and that IPLEX arrested the physical degeneration caused by Plaintiff's disease, it cannot be said that Defendant necessarily could complete its performance within one year. To accept the argument that an outside occurrence might obviate the need for contract completion, thereby removing the contract from the reaches of the Statute of Frauds, would eviscerate the statute.

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[42](...continued)
NY GOL §5-701(a)(1).

[43] When the Court addressed the Preliminary Injunction and Rule 12(b)(6) motions, it understood that the purported agreement was for Insmed to support Plaintiff's application for compassionate use of IPLEX. Indeed, in the Preliminary injunction motion, Plaintiff sought an order: (1) requiring Defendant to "provide to [Plaintiff] a written statement directed to the United States Food and Drug Administration ("FDA") in a form customary for such submissions supporting the 'compassionate use' of . . . IPLEX for Angeline Cacchillo, stating that Insmed, Inc. will, without reservation, provide Angeline Cacchillo the medication IPLEX at cost upon the granting of her compassionate use application by the FDA"; and (2) "directing Insmed Inc., in the event that Angeline Cacchillo's application is granted by the FDA, to provide Angeline Cacchillo IPLEX according to the amount allowed by the FDA's compassionate use grant and subject to Angeline Cacchillo's agreement to compensate Insmed, Inc. for the cost of the IPLEX thereby provided." This obligation, as opposed to the obligation to supply IPLEX for an indefinite period of time, is not necessarily barred by NY GOL §5-701(a)(1).

Under such reasoning, every contract would fall outside the Statute of Frauds because of the possibility that some outside event might occur that would render completion unnecessary or impossible. The facts here do not present an exception to the writing requirement for the purported contract. See Darby Trading Inc. v. Shell Intern. Trading and Shipping Co. Ltd., 568 F. Supp.2d 329, 339 (S.D.N.Y. 2008);[44] Borsack v. Chalk & Vermilion Fine Arts, Ltd., 974 F. Supp. 293, 298 n.3 (S.D.N.Y. 1997);[45] City of Yonkers v. Otis Elevator Co., 649 F. Supp. 716, 727 (S.D.N.Y. 1986).[46]

3. Conclusion - Contract Claim

For the reasons discussed above, the contract claim must be dismissed.

b. Fraud

The Court next addresses Plaintiff's fraud claim. "The elements of a cause of action for fraud require a material misrepresentation of a fact, knowledge of its falsity, intent to induce reliance, justifiable reliance by the plaintiff and damages." Eurycleia Partners, LP v. Seward & Kissel, LLP, 12 N.Y.3d 553, 559 (2009)(citing Ross v. Louise Wise Servs., Inc., 8 N.Y.3d 478, 488 (2007)). Plaintiff contends that Insmed, through its press releases, website postings, and Christy O'Neal and Amy Bartlett's statements, falsely assured Plaintiff that she would receive IPLEX at the end of the trial; that Defendant, knowing the promise was false, did so to induce Plaintiff to participate in the

[44]("Here, the "arrangement," as Plaintiff describes it in its Complaint, did not provide any means for [defendant] to discharge its performance obligations within one year. As such, the supposed contract presents a classic example of the Statute of Frauds.")

[45]("Where an alleged contract, as here, is indefinite as to duration and does not, by its terms, permit the defendant to discharge its performance obligations in less than one year, the statute requires a writing setting forth the essential terms of the agreement.")

[46]("[W]here no provision of the agreement alleged permits the defendants to discharge that performance obligation in less than a year, the Statute of Frauds applies.")

Phase IIB Trial; that Plaintiff participated in the trial in reliance on the false promise of a post-trial supply of IPLEX; and that Plaintiff was damaged by "subjecting her body to the rigors of the MMD1 trial." Pl. MOL p. 41.

1. Material Misrepresentation

As to a material misrepresentation, Plaintiff points to press releases and other statements from Insmed indicating that in MMD1 trials, subjects taking IPLEX experienced an improvement in lean muscle mass, gastrointestinal function, endurance and cognitive function. See Def. Ex. 30 & 31. Plaintiff contends that these statements induced her (at least in part) to enter the clinical trial, but she has not provided sufficient evidence indicating that the statements were false.

Plaintiff also points to public statements from Insmed indicating that the company had supported an equivalent of "compassionate use" of IPLEX for patients suffering from diseases other than MMD1. Again, Plaintiff has failed to present sufficient evidence of the falsity of these statements.

Plaintiff next points to an August 2007 web page statement that contained solicitations to physicians who might have been interested in securing compassionate use access to IPLEX for patients either through "a treatment IND," or a "single patient IND." See Def. Ex. 14. Plaintiff contends that this statement, together with the other statements, created the inference that Insmed had a policy of providing IPLEX to trial participants who saw benefit from it. However, it is undisputed that Insmed did not have a policy with respect to compassionate use requests from MMD1 patients. DSOF ¶ 138. Further, even if the statement is a representation that Insmed had such a policy, there is no dispute that Insmed's web site posting did not state that Insmed would support a Phase IIB clinical trial

subject's compassionate use application. DSOF ¶ 104. "Plaintiff testified that the Insmed's website did not promise potential clinical trial subjects that they would receive IPLEX via the compassionate use program if it was found safe and effective for them." Id. ¶ 105.

Still further, the August 2007 web page statement is, at most, a promise of future conduct contingent on several factors. See R. Cacchillo 12/17/10 Aff., ¶ 8. In this regard, the statement purportedly promised that "[s]hould a physician decide to seek IPLEX for the treatment of a patient, he or she should contact Insmed. Insmed will provide a 'drug supply reference statement' that acknowledges Insmed's commitment to supply IPLEX for the IND upon approval to the requesting physician." Id. Thus, the promise of a "drug supply reference letter" is contingent upon a physician deciding to seek IPLEX for the treatment of Plaintiff. This, in turn, is contingent on a physician determining that "the [Plaintiff] has no comparable or satisfactory alternative therapy available to . . . treat [MMD1], and that the probable risk to the person from the investigational drug . . . is not greater than the probable risk from [MMD1]." 21 U.S.C. § 360bbb(b)(1). These facts were unknown in August 2007.[47]

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[47]Robert Cacchillo's affidavit does not expressly state that the August 2007 web statement was directed to MMD1 patients, see R. Cacchillo 12/17/10 Aff., but rather it seems to be Plaintiff's contention that the statement was a representation of Insmed's policy regarding compassionate use for all disease which sought to to use IPLEX as a treatment. See, Pl. MOL., p. 7. However, there is no dispute that Insmed did not have a blanket policy regarding compassionate use of IPLEX for MMD1 patients. DSOF ¶ 138.

Further, to the extent that Plaintiff asserts that the August 2007 web statement was the same as the February 12, 2009 Insmed press release, the later, when read in context, appears to address compassionate use only as applied to ALS patients. See Def. Ex. 14(A). In this regard, the February 12, 2009 press release has two underlined subheading: "Myotonic Muscular Dystrophy (MMD)," and "Amyotrophic Lateral Sclerosis (ALS)." The "Myotonic Muscular Dystrophy (MMD)" subheading is near the top of the page, above the "Amyotrophic Lateral Sclerosis (ALS) subheading. The language addressing compassionate use follows the ALS subheading. Still further, the handwritten portion of the exhibit contains a statement immediately before the discussion of compassionate use which provides: "Insmed has discussed regulatory alternatives with the (continued...)

It is well settled that a promise made but not kept is not actionable as a fraud unless the promise was made with a then-existing intention not to perform. See Affiliated Credit Adjustors, Inc. v. Carlucci & Legum, 139 A.D.2d 611, 613 (2d Dep't 1988); see also Landes v. Sullivan, 235 A.D.2d 657, 659 (3d Dep't 1997).[48] Plaintiff has failed to provide sufficient evidence that the August 2007 statement was made with a then-existing intention not to perform. Rather, she surmises that, because Insmed did not support her compassionate use request when she made it in 2009, Insmed made the 2007 web statement with the intention not to perform. However, as indicated above, it is undisputed that Insmed's web site posting did not state that Insmed would support a Phase IIB clinical trial subject's compassionate use application, DSOF ¶ 104, and that Insmed did not have a standard policy regarding MMD1 patient's compassionate use applications. Id. ¶ 138. These undisputed facts do not support an inference that the 2007 statement was made with the then-existing intention not to provide Plaintiff a drug supply reference letter in 2009.

As to conversations, Plaintiff points to a September 13, 2007 conversation she and her husband had with Insmed's Clinical Research and Study Manager Christy O'Neal. During the conversation, Mr. Cacchillo referred to a pamphlet entitled "Volunteering For A Clinical Trial" and advised Ms. O'Neal that the pamphlet stated that a patient with a serious disease who does well at a clinical trial will generally be kept on the medication at

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[47](...continued)
FDA[.]" At approximately this same time in 2009, the FDA announced its position that it would allow expanded access of IPLEX for ALS patients. DSOF ¶ 168.

[48](An "opinion or a prediction of something which is hoped or expected to occur in the future will not sustain an action for fraud.")

the end of the trial. RC pp. 131-132. Mrs. O'Neal purportedly stated: "Yes, pharmaceutical companies generally do that." Id. p. 132. Ms. O'Neal's statement was merely that some pharmaceutical companies support compassionate use following a clinical trial, but, as Plaintiff acknowledges, O'Neal did not indicate that Insmed did so. See AC p. 112.[49] Inasmuch as some pharmaceutical companies do support compassionate use following a clinical trial, the statement itself was not false. Moreover, Plaintiff testified that she does not believe that Ms. O'Neal lied to her when making the statement. AC p. 113; see also RC pp. 134-135, 258.

Plaintiff also points to Amy Bartlett's statement at the April 7, 2008 pre-trial screening at OSU when, after Plaintiff's husband asked Ms. Bartlett "what happens at the end of the trial if she gets the drug and she does well," Ms. Bartlett responded: "They'll put her on compassionate care." While Ms. Bartlett's statement was the most direct assurance of a post-trial supply of IPLEX, Ms. Bartlett did not work for Insmed or have the authority to represent it. Further, assuming she had apparent authority,[50] her statement was conditioned on Plaintiff doing well on IPLEX. At the time, it was unknown whether Plaintiff would be administered IPLEX or a placebo, or, if she was administered IPLEX,

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[49]Plaintiff testified that Ms. O'Neal "did not say that Insmed would support [a compassionate use application] per se. She did not mention Insmed." AC p. 112. Rather, according to Plaintiff, Ms. O'Neal "made it sound like that was the general practice. At the same time, she didn't say that Insmed — she didn't say that Insmed would not support – that Insmed did not participate in that type of thing. She did not say that for this particular trial compassionate use could not be available . . . ." Id.

[50]While Ms. Bartlett worked for OSU, there were numerous facts from which a reasonable fact finder could conclude that Ms. Bartlett had apparent authority to speak on behalf of Insmed. See Hallock v. State, 64 N.Y.2d 224, 231, 485 N.Y.S.2d 510, 474 N.E.2d 1178 (1984)("Essential to the creation of apparent authority are words or conduct of the principal, communicated to a third party, that give rise to the appearance and belief that the agent possesses authority to enter into a transaction."). Among these were the facts indicating that Ms. Bartlett was acting as a coordinator or liaison between Insmed and the trial participants. See fn. 22, *supra*.

whether she would do well on it. It was also unknown whether a physician would support an individual IND for IPLEX for Plaintiff. Thus, Ms. Bartlett's statement amounted to, at most, a promise or an opinion as to future events that were hoped or expected to occur. As such, it is not actionable as a fraud claim. Moreover, Plaintiff has failed to provide sufficient evidence that the statement was made with a then-existing intention not to perform.[51]

2. Intent to Induce Reliance, and Justifiable Reliance Thereon

Plaintiff must also establish that Defendant made a knowing misrepresentation with the intent to induce reliance, and that Plaintiff justifiably relied on the misrepresentation. Plaintiff has failed to meet this standard.

The evidence establishes that Plaintiff had been trying to obtain IPLEX since 2005, and had previously attempted to enroll in the Phase IIA Trial without any promise of post-trial IPLEX. See DSOF ¶¶ 1-10. She also attempted to obtain IPLEX off-label through Christine Quinn and Dr. Zhou, and went to considerable lengths to gain access to IPLEX through the OSU Phase IIB Trial.

While Plaintiff points to several statements that she contends falsely promised compassionate care use of IPLEX following the trial, there is insufficient evidence that Plaintiff relied on these statements about compassionate use when determining whether to enter the Phase IIB Trial. Plaintiff testified that, when she agreed to entered the Phase IIB Trial, she was hoping for a Phase III trial after the Phase IIB Trial concluded, not that

[51]Indeed, the undisputed evidence indicates that after the trial concluded, Bartlett attempted to aid Plaintiff in securing "compassionate use" of IPLEX from Insmed. It is counterintuitive to conclude that Bartlett made the statement at the beginning of the trial with knowledge of its falsity, or with the then-present intention not to perform, only to make considerable efforts to secure IPLEX for Plaintiff at the end of the trial.

she was relying on IPLEX being supplied via compassionate care. AC pp. 214-15. Plaintiff's position was confirmed by her husband, who stated that even if they had never spoken to Christine O'Neal about compassionate care, Plaintiff would have agreed to participate in the clinical trial because she might have received the drug during the trial and because they were "looking at a phase III." RC p. 147. Similarly, Plaintiff testified that she "wasn't looking for compassionate use unless there was no other means of staying on the drug." AC pp. 214-15. Moreover, the evidence indicates that in February 2009, when the Cacchillos were getting "panicky" because they had not heard anything about the results of the Phase IIB Trial or a future phase III trial, Mr. Cacchillo went to Insmed's website and read the February 12, 2009 press release that discussed a compassionate care option for receiving IPLEX. Mr. Cacchillo testified that, upon seeing the information, he was "excited" and "all psyched up" because, as he told his wife, compassionate care offered a hopeful potential to receive IPLEX "if phase III doesn't come." RC pp. 158-61. The testimony indicates that, until that point, compassionate care was not the determining factor in Plaintiff's decision to participate in the Phase IIB Trial. Because Plaintiff's decision to participate in the trial was not dependent on any statements made by Defendant about post-trial compassionate care use of IPLEX, she cannot establish reliance as a matter of law. See J.A.O. Acquisition Corp. v. Stavistsky, 8 N.Y.3d 144, 148 (2007).[52]

The record further establishes that Plaintiff could not, as a matter of law, reasonably rely on any of the statements she identified. Whether considered individually

[52](holding reliance not established where defendant's statements had no impact on plaintiff's decision to act)

or in total, the statements were so vague and indefinite that no reasonable person would have felt assured that Insmed would supply her with IPLEX indefinitely, regardless of whether the Phase IIB Trial results were positive. See George Backer Mgmt. Corp. v. Acme Quilting Co., 46 N.Y.2d 211, 220 (1978).[53]

3. Fraud - Conclusion

For these reasons, the fraud claim must be dismissed.

d. Negligent Misrepresentation

Last, the Court addresses Plaintiff's negligent misrepresentation claim. To establish a claim for negligent misrepresentation, Plaintiff must establish: "(1) the existence of a special or privity-like relationship imposing a duty on the defendant to impart correct information to the plaintiff; (2) that the information was incorrect; and (3) reasonable reliance on the information." Mandarin Trading Ltd. v. Wildenstein, 16 N.Y.3d 173, 180 (2011)(internal quotation marks and citation omitted); see also Hydro Investors, Inc. v. Trafalgar Power Inc., 227 F.3d 8, 20 (2d Cir. 2000).[54] On the second element, Plaintiff must establish that Defendant provided incorrect information. "[T]he alleged misrepresentation must be factual in nature and not promissory or relating to future events that might never come to fruition." Hydro Investors, 227 F.3d at 20-21. "Promises of future conduct are not actionable as negligent misrepresentations." Murray v. Xerox Corp.,

[53](holding that vague, indefinite statements of opinion concerning future events sets forth no reasonable grounds for reliance)

[54] ("Under New York law, the elements for a negligent misrepresentation claim are that (1) the defendant had a duty, as a result of a special relationship, to give correct information; (2) the defendant made a false representation that [it] should have known was incorrect; (3) the information supplied in the representation was known by the defendant to be desired by the plaintiff for a serious purpose; (4) the plaintiff intended to rely and act upon it; and (5) the plaintiff reasonably relied on it to his or her detriment.")(citations omitted)

811 F.2d 118, 123 (2d Cir. 1987).

The misrepresentations in issue in this case were related to future conduct and future events. As indicated above with regard to the fraud claim, the misrepresentations in issue concerned whether Plaintiff would receive IPLEX follow the Phase IIB Trial. The answer to this question depended on: (1) whether Plaintiff received IPLEX during the Phase IIB Trial (as opposed to a placebo); (2) whether Plaintiff did well on the drug; (3) whether the Phase IIB Trial as a whole was deemed successful enough to warrant a Phase III Trial; (4) whether Defendant determined to continue with clinical tests in an attempt to obtain FDA approval for IPLEX as a treatment for MMD1, and (5) whether a physician would come forward to support an individual IND for IPLEX for Plaintiff. Because the answer to each of these questions was unknown at the time each alleged misrepresentation was made, none constitutes an actionable misrepresentation of present fact. Rather, each was a promises of future conduct. As such, the underlying misrepresentations are not actionable and the negligent misrepresentation claim must be dismissed. Hydro Investors, 227 F.3d at 20-21; Murray, 811 F.2d at 123; Sheth v. New York Life Ins. Co., 709 N.Y.S.2d 74, 75 (1st Dep't 2000);[55] Bango v. Naughton, 184 A.D.2d 961, 963 (3d Dep't 1992);[56] Margrove Inc. v. Lincoln First Bank of Rochester, 54 A.D.2d

[55]("The purported misrepresentations relied upon by plaintiffs may not form the basis of a claim for fraudulent and/or negligent misrepresentation since they are conclusory and/or constitute mere puffery, opinions of value or future expectations.") (citations omitted)

[56](negligent misrepresentation claim was properly dismissed for failure to state a claim because the alleged representations were "mere expressions of future expectation") (internal quotation and citation omitted)

1105, 1107 (4th Dep't 1976).[57]

IV. CONCLUSION

For the reasons set forth above, Defendant's motion for summary judgment [dkt. # 64] is **GRANTED** and the action is **DISMISSED.**

IT IS SO ORDERED.

Dated: February 19, 2013

Thomas J. McAvoy
Senior, U.S. District Judge

[57]("The alleged negligent misstatements all relate to promised future conduct, if misstatements they be, and there is a lack of any element of misrepresentation as to an existing material fact so as to come within the doctrine of negligent misrepresentation....")